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			1637	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/000,256

Applicant(s)

SUN ET AL.

Examiner

Teresa E Strzelecka

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 March 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5,7,8,15 and 18 is/are pending in the application.
- 4a) Of the above claim(s) 18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 7, 8, 15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

1. This office action is in response to an amendment filed March 9, 2004. Claims 1-17 were previously pending, with claims 6, 9-14 and 16 withdrawn from consideration. Applicants amended claims 1 and 15, canceled claims 6, 9-14, 16 and 17 and added new claim 18. Claims 1-5, 7, 8, 15 and 18 are pending.

2. Newly submitted claim 18 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the claim is drawn to a nucleic acid sequence that encodes an amino acid sequence of SEQ ID NO: 198. This claim encompasses nucleic acid sequences which are different from SEQ ID NO; 84 elected by Applicants.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 18 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

3. Claims 1-5, 7, 8 and 15 will be examined.

4. Applicants' claim cancellations overcame the following rejections: rejection of claim 17 under 35 U.S.C. 101, utility and rejection of claim 17 under 35 U.S.C. 112, first paragraph, enablement. All of the other previously presented rejections are maintained for reasons given below in the "Response to Arguments" section.

Response to Arguments

5. Applicant's arguments filed March 9, 2004 have been fully considered but they are not persuasive.

A) Regarding the rejection of claims 1-5, 7, 8 and 15 under 35 U.S.C. 101, utility, and the rejection under 35 U.S.C. 112, first paragraph, enablement, Applicants argue that from the

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description of SEQ ID NO: 84 it is clear that SEQ ID NO: 84 shows expression only in prostate cancer tissue, and that “The case law on utility is quite clear; mere identification of a pharmacological activity of a claimed compound that is relevant to an asserted pharmacological use provides an immediate benefit to the public and thus satisfies the utility requirement. *Nelson v. Bowler*, 626 F-2d 853, 206 USPQ 881, 883 (CCPA 1980).”.

However, Applicants did not show either that the nucleic acid with SEQ ID NO: 84 is expressed only in prostate cancer tissue or that it has any “pharmacological activity”. The only fact Applicants can assert with respect to SEQ ID NO: 84 is that this sequence seems to be expressed in prostate tissue based on the results of a computerized database search of a single database. Such data is totally inconclusive, as other databases or results published somewhere else may show that SEQ ID NO: 84 is expressed in normal prostate tissue as well. Further, even if one were to rely on that single database, the question of the comparative level of expression of SEQ ID NO: 84 in cancerous vs. normal tissue, critical to the utility of SEQ ID NO: 84 as being indicative of tumorigenesis, remains unanswered. In order for SEQ ID NO: 84 to be diagnostic for prostate cancer, its level of expression in prostate cancer cells would have to be significantly higher than in normal prostate cells. Applicants have not provided a conclusive evidence that this is indeed the case.

The rejections are maintained.

B) Regarding the rejection of claims 1-5, 7, 8 and 15 under 35 U.S.C. 112, first paragraph, written description, Applicants argue that the amendment to claim 1, introducing a limitation of stringent hybridization conditions to part c) and a limitation of at least 85% sequence identity in part (d), as well as the limitation of being detectable in prostate cancer tissue, overcomes the rejection.

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However, Applicants did not describe any nucleic acids which hybridize to SEQ ID NO: 84 under stringent conditions, or any nucleic acids which have at least 85% sequence identity to SEQ ID NO: 84. Further, the limitation of the nucleic acid being detectable in prostate cancer tissue is not relevant, as it does not impose any structural limitation on the nucleic acid sequence.

The rejection is maintained.

C) Regarding the rejection of claims 1, 2, 4, 5, 7 and 8 under 35 U.S.C. 102(a) over a sequence with accession No. AK027241, Applicants argue that an amendment including a limitation of “a nucleic acid molecule that exhibits substantial sequence similarity to at least 300 nucleotides of SEQ ID NO: 84” and a limitation of hybridizing to SEQ ID NO: 84 under stringent conditions overcome this rejection. Applicants defined “substantial similarity” the following way: “The term “substantial similarity” or “substantial sequence similarity,” when referring to a nucleic acid or fragment thereof, indicates that, when optimally aligned with appropriate nucleotide insertions or deletions with another nucleic acid (or its complementary strand), there is nucleotide sequence identity in at least about 50%, more preferably 60% of the nucleotide bases, usually at least about 70%, more usually at least about 80%, preferably at least about 90%, and more preferably at least about 95-98% of the nucleotide bases, as measured by any well-known algorithm of sequence identity, such as FASTA, BLAST or Gap” (specification, page 14, lines 1-8).

However, sequence with accession No. AK027241 is identical to SEQ ID NO: 84 over bp 5-687, i.e., over 683 bp with no mismatches, and over bp 5-936 with only 4 mismatches, therefore it fulfills both requirements, i.e. being “substantially identical” to at least 300 bp of SEQ ID NO: 84 and hybridizing under stringent conditions to SEQ ID NO: 84.

The rejection is maintained.

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D) Regarding the rejection of claims 1, 2, 4, 5, 7 and 8 under 35 U.S.C. 102(b) over a sequence with accession No. AF0123851, Applicants argue that an amendment including a limitation of “a nucleic acid molecule that exhibits substantial sequence similarity to at least 300 nucleotides of SEQ ID NO: 84” and a limitation of hybridizing to SEQ ID NO: 84 under stringent conditions overcome this rejection.

Applicants defined “substantial similarity” the following way: “The term “substantial similarity” or “substantial sequence similarity,” when referring to a nucleic acid or fragment thereof, indicates that, when optimally aligned with appropriate nucleotide insertions or deletions with another nucleic acid (or its complementary strand), there is nucleotide sequence identity in at least about 50%, more preferably 60% of the nucleotide bases, usually at least about 70%, more usually at least about 80%, preferably at least about 90%, and more preferably at least about 95-98% of the nucleotide bases, as measured by any well-known algorithm of sequence identity, such as FASTA, BLAST or Gap” (specification, page 14, lines 1-8).

The sequence with accession No. AF0123851 is 99.6% identical to 261 bp of SEQ ID NO: 84, with only a single mismatch, therefore, according to Applicants’ definition of “substantial similarity”, this sequence is substantially similar to at least 300 bp of SEQ ID NO: 84. Further, since there is only a single base pair mismatch in the 261 bp, 14 bp from the 3’ end of that sequence, it would hybridize under stringent conditions to SEQ ID NO: 84.

The rejection is maintained.

E) Regarding the rejection of claim 15 under 35 U.S.C. 102 (b) as being anticipated by GibcoBRL catalog, Applicants argue that the kit claimed comprises a means for determining the presence of a nucleic acid molecule comprising:“(a) a nucleic acid sequence that encodes an amino acid sequence of SEQ ID NO: 198; (b) nucleic acid sequence of SEQ ID NO:84; (d) a nucleic acid

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sequence that exhibits substantial sequence similarity to at least 300 nucleotides of the nucleic acid molecule of (a) or (b) and hybridizes under stringent hybridization conditions of 50% formamide/6x SSC at 42 C for at least 10 hours or 6X SSC at 68 C without formamide for at least 10 hours to the nucleic acid molecule of (a) or (b); or (d) a nucleic acid molecule having at least 85% sequence identity over the entire length of the nucleic acid molecule of (a) or (b).”

Applicants claim “means for determining a nucleic acid molecule”. The Gibco BRL catalog teaches means for detecting any nucleic acid molecule, since they teach a kit comprising random primers, therefore this reference anticipates claim 15.

The rejection is maintained.

Claim Rejections - 35 USC § 101

6. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

7. Claims 1-5, 7, 8, 15 and 17 are rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility.

The current claims are drawn to a an isolated nucleic acid molecule comprising SEQ ID NO: 84, a nucleic acid which that exhibits substantial sequence similarity to at least 300 nucleotides of the nucleic acid comprising SEQ ID NO: 84 and hybridizes under stringent conditions to SEQ ID NO: 84 or a nucleic acid having at least 85% sequence identity over the entire length of SEQ ID NO: 84.

Credible Utility

Following the requirements of the Utility Guidelines (See: Federal Register: December 21, 1999 (Volume 64, Number 244), revised guidelines for Utility.), the first inquiry is whether a

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credible utility is cited in the specification for use of the nucleic acids. The only cited utilities identified by the examiner are as probes and primers (pages 40-44), protein expression (pages 44-53), production of transgenic animals and cells (pages 88-92), diagnosis of prostate cancer (pages 95-102), detection of non-cancerous prostate disease (page 102-103), identifying prostate tissue (page 103-104). These utilities are credible.

Upon identification of credible utilities, the next issue is whether there are any well established utilities for the nucleic acid comprising SEQ ID NO: 84. No well established utilities for this specific nucleic acid are identified in either the specification.

Substantial utility

Given the absence of a well established utility, the next issue is whether substantial utilities are disclosed in the specification. Here, as provided by the specification, nucleic acid with SEQ ID NO: 84 has been identified by data mining of sequences in the Incyte Genomics LIFESEQ® database using CLASP software (page 116), and SEQ ID NO: 84 was identified as a CLASP2 sequence, which means that it has detectable expression only in cancer tissue. The level of expression is shown on page 122 as .0013. No further explanations were provided in the specification regarding SEQ ID NO: 84. It is not clear what was the source of the nucleic acid (cell culture or tumor) and what was the level of expression of SEQ ID NO: 84 in cancer vs. normal cells, therefore it is not clear how a nucleic acid molecule comprising SEQ ID NO: 84 could be used for detection of prostate malignancies, for example.

As noted in the utility guidelines, methods of treating unspecified diseases, basic research on a product to identify properties, intermediate products which themselves lack substantial utility are all insubstantial utilities (see page 6 of the Utility guideline training materials). In the instant case,

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additional research would be necessary to establish substantial utility of a nucleic acid comprising SEQ ID NO: 84.

In order for a polynucleotide to be useful for diagnosis of a disease, there must be a well-established or disclosed correlation or relationship between the claimed polynucleotide and a disease or disorder. The presence of a polynucleotide in prostate tissue cells is not sufficient for establishing a utility in diagnosis of disease in the absence of some information regarding a correlative or causal relationship between the expression of the claimed cDNA and the disease. If a molecule is to be used as a surrogate for a disease state, some disease state must be identified in some way with the molecule. There must be some expression pattern that would allow the claimed polypeptide to be used in a diagnostic manner. Many proteins are expressed in normal tissues and diseased tissues. Therefore, one needs to know, e.g., that the claimed polynucleotide is either present only in cancer tissue to the exclusion of normal tissue or is expressed in higher levels in diseased tissue compared to normal tissue (i.e. overexpression). Evidence of a differential expression might serve as a basis for use of the claimed polynucleotide as a diagnostic for a disease. However, in the absence of any disclosed relationship between the claimed polynucleotide or the protein that is encoded thereby and any disease or disorder and the lack of any correlation between the claimed polynucleotide or the encoded protein with any known disease or disorder, any information obtained from an expression profile would only serve as the basis for further research on the observation itself. "Congress intended that no patent be granted on a chemical compound whose sole 'utility' consists of its potential role as an object of use-testing." *Brenner*, 148 USPQ at 696. The disclosure does not present a substantial utility that would support the requirement of 35 U.S.C. §101.

Specific Utility

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In the current case, even if the substantial utility argument above were found unpersuasive, then the substantial utility of the nucleic acid comprising SEQ ID NO: 84 is, at best, a relationship to an association with prostate tissue. This utility is not specific because there are a lot of different nucleic acids expressed in prostate tissue, 136 of them provided by Applicants. Thus, the presence of the nucleic acids in prostate tissue does not provide a specific utility because there is no direct or even indirect connection made between any particular utility and the nucleic acid comprising SEQ ID NO: 84. Therefore, even though Applicants claim that the nucleic acids could be used in detection and monitoring of prostate cancer, no specific association between the prostate cancer and SEQ ID NO: 84 has been provided, and thus, no specific utility for SEQ ID NO: 84.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 1-5, 7, 8 and 15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Factors to be considered in determining whether a disclosure meets the enablement requirement of 35 USC 112, first paragraph, have been described by the court in *In re Wands*, 8 USPQ2d 1400 (CA FC 1988). *Wands* states at page 1404,

“Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized by the board in *Ex parte Forman*. They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature

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of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.”

The nature of the invention and breadth of claims

Claims 1-5, 7, 8 and 15 are drawn to an isolated nucleic acid molecule comprising SEQ ID NO: 84, a nucleic acid which that exhibits substantial sequence similarity to at least 300 nucleotides of the nucleic acid comprising SEQ ID NO: 84 and hybridizes under stringent conditions to SEQ ID NO: 84 or a nucleic acid having at least 85% sequence identity over the entire length of SEQ ID NO: 84. Applicants assert that nucleic acids with SEQ ID NO: 1-136 can be used for diagnosis of prostate cancer (pages 95-102), detection of non-cancerous prostate disease (page 102-103), identifying prostate tissue (page 103-104). However, as will be further discussed, there is no support in the specification and prior art for the asserted use of the nucleic acid with SEQ ID NO: 84. The invention is a class of invention which the CAFC has characterized as “the unpredictable arts such as chemistry and biology.” *Mycogen Plant Sci., Inc. v. Monsanto Co.*, 243 F.3d 1316, 1330 (Fed. Cir. 2001).

Working Examples

The specification has no working examples of using a nucleic acid with SEQ ID NO: 84 for detection of prostate cancer, non-cancerous prostate disease or in identifying prostate tissue.

Guidance in the Specification.

The specification provides no evidence that the disclosed nucleic acid sequences can be in fact used for detection of prostate cancer, non-cancerous prostate disease or in identifying prostate tissue. The guidance provided by the specification amounts to an invitation for the skilled artisan to try and follow the disclosed instructions to make and use the claimed invention. The specification merely discloses that nucleic acid with SEQ ID NO: 84 has been identified by data mining of sequences in the Incyte Genomics LIFESEQ® database using CLASP software (page 116), and

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SEQ ID NO: 84 was identified as a CLASP2 sequence, which means that it has detectable expression only in cancer tissue. The level of expression is shown on page 122 as .0013. No further explanations were provided in the specification regarding SEQ ID NO: 84. It is not clear what was the source of the nucleic acid (cell culture or tumor) and what was the level of expression of SEQ ID NO: 84 in cancer vs. normal cells, therefore it is not clear how a nucleic acid molecule comprising SEQ ID NO: 84 could be used for detection of prostate malignancies, for example.

The unpredictability of the art and the state of the prior art

Applicants did not show what type of cells nucleic acid with SEQ ID NO: 84 was obtained from, i.e., whether these cells were from tissue culture or primary tumors. At the time the invention was made, it was known in the prior art that observations of genetic status in cancer cell lines are frequently not observable in primary tumor tissues. For example, Sidransky *et al.* (US 5856094; cited in the previous office action) teach that although the rate of a homozygous deletion of P16 ranged from 40-60% of breast cancer cell lines, neither homozygous deletions nor point mutations are typically observed in primary breast carcinomas (Col. 2, lines 9-14). The suitability of cell lines in general as models for primary tumors is also questioned in the prior art. For example, Dermer (Bio/Technology, Vol. 12, March 1994, p. 320; cited in the previous office action) teaches that “[w]hen a normal or malignant body cell survives a crisis period and adapts to immortal life in culture, it takes an evolutionary-type step that enables the new cell line to thrive in its artificial environment... Yet normal or malignant cells in vivo are not like that. This means that cell lines are really a new life form on Earth, neither human nor animal. Evidence of the contradictions between life on the bottom of the lab dish and in the body has been in the scientific literature for more than 30 years, evidence that has been systematically ignored by the cancer establishment (first column).”

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Therefore, if the cells considered were cell culture cells, then it is even more problematic if SEQ ID NO: 84 could be used for detection of prostate tumors from patients' tissues.

Quantity of Experimentation

The quantity of experimentation in this area is extremely large since there is significant number of parameters which would have to be studied to enable using of nucleic acids with SEQ ID NO: 84 for the detection of prostate malignancies or prostate tissue. A person of skill in the art would have to perform detection studies of SEQ ID NO: 84 in normal and malignant prostate tissues from cell culture and patients' samples, as well as in cells from unrelated tissues, to determine whether there is a difference in the expression levels of SEQ ID NO: 84 in all of these types of cells, and association of SEQ ID NO: 84 with prostate malignancies. Significance of the increased expression levels needs to be established, as there are usually variations in tissues obtained from different individuals, therefore studies involving statistically significant numbers of patients would also need to be performed.

Conclusion

Given the broad claims in an art whose nature is identified as unpredictable, the unpredictability of that art, the large quantity of research required to define these unpredictable variables, the lack of guidance provided in the specification, the absence of a working example it is the position of the examiner that it would require undue experimentation for one of skill in the art to use the claimed nucleic acids for prostate malignancies detection.

10. Claims 1-5, 7 and 8 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not

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described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1-5, 7 and 8 are drawn to an isolated nucleic acid molecule comprising SEQ ID NO: 84, a nucleic acid which that exhibits substantial sequence similarity to at least 300 nucleotides of the nucleic acid comprising SEQ ID NO: 84 and hybridizes under stringent conditions to SEQ ID NO: 84 or a nucleic acid having at least 85% sequence identity over the entire length of SEQ ID NO: 84.

In analysis of the claims for compliance with the written description requirement of 35 U.S.C. 112, first paragraph, the written description guidelines note regarding genus/species situations that "Satisfactory disclosure of a ``representative number" depends on whether one of skill in the art would recognize that the applicant was in possession of the necessary common attributes or features of the elements possessed by the members of the genus in view of the species disclosed." (See: Federal Register: December 21, 1999 (Volume 64, Number 244), revised guidelines for written description.)

All of the current claims encompass a genus of nucleic acids which are different from those disclosed in the specification. The genus includes variants for which no written description is provided in the specification. This large genus is represented in the specification by only the particularly named SEQ ID No: 84. Thus, applicant has express possession of only one particular nucleic acid, in a genus which comprises hundreds of millions of different possibilities. Here, no common element or attributes of the sequences are disclosed, not even the presence of certain domains. No structural limitations or requirements which provide guidance on the identification of sequences which meet these functional limitations is provided. No written description of alleles, of

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upstream or downstream regions containing additional sequence has been provided in the specification.

It is noted in the recently decided case The Regents of the University of California v. Eli Lilly and Co. 43 USPQ2d 1398 (Fed. Cir. 1997) decision by the CAFC that

“A definition by function, as we have previously indicated, does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is. See *Fiers*, 984 F.2d at 1169- 71, 25 USPQ2d at 1605- 06 (discussing *Amgen*). It is only a definition of a useful result rather than a definition of what achieves that result. Many such genes may achieve that result. The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See *In re Wilder*, 736 F.2d 1516, 1521, 222 USPQ 369, 372- 73 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate."). Accordingly, naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material. “

In the current situation, the definition of the SEQ ID NO: 84 lack any specific structure, is precisely the situation of naming a type of material which is generally known to likely exist, but, except for one specific SEQ ID NO, is in the absence of knowledge of the material composition and fails to provide descriptive support for the generic claim to “a nucleic acid having at least 85% sequence identity over the entire length of SEQ ID NO: 84”, for example.

It is noted that in *Fiers v. Sugano* (25 USPQ2d, 1601), the Fed. Cir. concluded that

“...if inventor is unable to envision detailed chemical structure of DNA sequence coding for specific protein, as well as method of obtaining it, then conception is not achieved until reduction to practice has occurred, that is, until after gene has been isolated...conception of any chemical substance, requires definition of that substance other than by its functional utility.”

In the instant application, certain specific SEQ ID NOs are described. Also, in *Vas-Cath Inc. v. Mahurkar* (19 USPQ2d 1111, CAFC 1991), it was concluded that:

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"...applicant must also convey, with reasonable clarity to those skilled in art, that applicant, as of filing date sought, was in possession of invention, with invention being, for purposes of "written description" inquiry, whatever is presently claimed."

In the application at the time of filing, there is no record or description which would demonstrate conception of any nucleic acids other than those expressly disclosed which comprise SEQ ID NO: 84. Therefore, the claims fail to meet the written description requirement by encompassing sequences which are not described in the specification.

Claim Interpretation

11. Applicants defined "substantial similarity" the following way: "The term "substantial similarity" or "substantial sequence similarity," when referring to a nucleic acid or fragment thereof, indicates that, when optimally aligned with appropriate nucleotide insertions or deletions with another nucleic acid (or its complementary strand), there is nucleotide sequence identity in at least about 50%, more preferably 60% of the nucleotide bases, usually at least about 70%, more usually at least about 80%, preferably at least about 90%, and more preferably at least about 95-98% of the nucleotide bases, as measured by any well-known algorithm of sequence identity, such as FASTA, BLAST or Gap" (specification, page 14, lines 1-8).

Claim Rejections - 35 USC § 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

13. Claims 1, 2, 4, 5, 7 and 8 are rejected under 35 U.S.C. 102(a) as being anticipated by a sequence with accession No. AK027241 (September 29, 2000).

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Regarding claim 1, sequence with accession No. AK027241 (2119 bp) is 21.7% identical to SEQ ID NO: 84, with bp 5 to 936, i.e., 932 bp, 99.6% identical to bp 3259-4190 of SEQ ID NO: 84 (see sequence alignment). Therefore, sequence with accession No. AK027241 fulfills the requirement of being “substantially similar to at least 300 bp of SEQ ID NO: 84” and will hybridize under stringent conditions to SEQ ID NO: 84.

Regarding claim 2, the nucleic acid with accession No. AK027241 is a cDNA.

Regarding claims 4 and 5, the nucleic acid with accession No. AK027241 is Homo sapiens cDNA.

Regarding claims 7 and 8, the nucleic acid was cloned in a pME18SFL3 vector, therefore it must have been used with host cells.

14. Claims 1, 2, 4 5, 7 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by a sequence with accession No. AF0123851 (April 23, 1998) and as evidenced by De Smet et al. (Bioch. Biophys. Res. Comm., vol. 241, pp. 653-657, 1997).

Regarding claim 1, sequence with accession No. AF0123851 (261 bp) is 6.1% identical to SEQ ID NO: 84, with bp 1 to 261 99.6% identical to bp 3695-3955 of SEQ ID NO: 84, with only one mismatch 14 bp from the 3' end (see sequence alignment). Therefore, sequence with accession No. AF0123851 fulfills the requirement of being “substantially similar to at least 300 bp of SEQ ID NO: 84” and will hybridize under stringent conditions to SEQ ID NO: 84.

Regarding claim 2, the nucleic acid with accession No. AF0123851 is a cDNA.

Regarding claims 4 and 5, the nucleic acid with accession No. AF0123851 is human testis cDNA.

Regarding claims 7 and 8, De Smet et al. Evidence that the cDNA clones were in pTZ18R plasmid and DH5 α F'IQ host cells (page 654, second paragraph).

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15. Claim 15 is rejected under 35 U.S.C. 102(b) as being anticipated by GibcoBRL Catalog (p. 7-7, 1993-94).

GibcoBRL catalog teaches a kit with random primers (hexamers), which are suitable for DNA synthesis (page 7.7). Therefore, since any DNA can be amplified with such primers, they can be used to detect the nucleic acid comprising SEQ ID NO: 84.

16. No claims are allowed.

Conclusion

17. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Teresa E Strzelecka whose telephone number is (571) 272-0789. The examiner can normally be reached on M-F (8:30-5:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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TS
May 3, 2004


JEFFREY FREDMAN
PRIMARY EXAMINER
5/4/04